



# Patent-eligibility of isolated DNA: another twist in the *Prometheus* debate

## THE CASE:

*Association for Molecular Pathology and Ors v Myriad Genetics, Inc and Ors*

US Court of Appeals for the Federal Circuit

16 August 2012

Following on from the *Prometheus* decision, Paul Hastings' **Bruce Wexler** offers commentary on the *Myriad* decision in terms of patent eligibility

**On 16 August 2012, the US Court of Appeals for the Federal Circuit decided *Ass'n for Molecular Pathology and Ors v Myriad Genetics, Inc and Ors*<sup>1</sup>, involving patent-eligibility of isolated gene sequences and diagnostic methods of identifying mutations in these sequences. As noted in our companion article, the Supreme Court ordered the Federal Circuit to consider this case anew in view of *Prometheus*. As discussed below, the Federal Circuit found patent eligibility for the majority of subject matter involved. The most controversial aspect involved patent eligibility of isolated gene sequences otherwise identical to those found in the human body. In this companion piece, we discuss the *Myriad* ruling, its relationship to the broader topic of patent eligibility, and practical implications of the decision.**

The *Myriad* patents encompassed three sets of claims:

- (1) Composition claims covering "isolated" human BRCA genes and mutations correlating to a predisposition to certain cancers (both synthetic DNA and that isolated from naturally occurring DNA);
- (2) A method claim covering the process of "screening" potential cancer therapeutics by growing cells, detecting their growth rate, and making comparisons in the presence or absence of the therapeutic; and
- (3) Method claims covering "analysing" or "comparing" a patient's gene sequence to a normal sequence to identify predisposition to certain cancers.

The least controversy concerned the method claims directed to analysing or comparing a patient's gene sequence to a normal sequence to identify predisposition to certain cancers. The Federal Circuit found they were "indistinguishable" from the ineligible claims in *Prometheus*, and indeed incorporated even fewer transformative physical steps. All three judges agreed on the outcome.

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As to the patent claim to a method of "screening" potential cancer therapeutics, all three judges agreed this was patent eligible. The court relied on the fact that the claim included the steps of growing *host cells transformed with an altered gene* in the presence or absence of a potential cancer

therapeutic. The court reasoned this was not just a law of nature, but rather the creation of a new, man-made form of cell that did not exist previously. The additional comparison and analysis steps did not make the subject matter unpatentable. The court thus adhered to *Prometheus's* admonition that there is nothing wrong *per se* with including a law of nature in a claim as long as the claim also has a substantial application of that law.

The court divided in resolving the remaining issues concerning patentability of isolated DNA sequences. As noted before, these claims involved two sub-categories: (a) synthetic cDNAs ("complementary DNAs"), and (b) isolated DNA sequences identical in form to sequences in the human body except for the structural changes occurring when they are separated from the larger DNA strand. The cDNAs were molecules synthesised by man from Messenger Ribonucleic acid (mRNA) having a structure different from any DNA sequences found in the human body. The cDNAs were noted to have physical properties, such as stability, not possessed by mRNA, and to have uses that human DNA cannot achieve, including to express a protein in a cell that does not normally produce it. The court thus rejected the argument that a new and man-made structure (cDNA) is ineligible if it finds "inspiration" from a natural product (mRNA). All three judges agreed that cDNAs are patent-eligible.

Each judge, however, held a different view on the patenting of isolated DNA sequences otherwise identical to sequences in the human body but for the structural changes occurring when removing them from the larger DNA

strand. At the outset, Judge Lourie held that *Prometheus* does not control because this is a composition of matter and not a method. Judge Lourie nonetheless did go on to discuss *Prometheus*, saying that it provided “valuable insights and illuminated broad, foundational principles”. Judge Moore and Judge Bryson stated that, while *Prometheus* does not control the outcome, it is “instructive” and its discussion ought to apply. It would thus be risky for litigants, at this point, to rest a claim of patent eligibility on an argument that *Prometheus* is irrelevant. Accordingly, regardless of claim form, litigants should be sure to consider the basic framework of *Prometheus*.

The judges all agreed that “laws of nature, natural phenomenon, and abstract ideas” are not patentable, and that this exclusion further applied to “mental processes” and “products of nature”. The judges analysed two important book-end Supreme Court cases involving patent-eligibility of products of nature: *Funk Brothers Seed Co v Kalo Inoculant Co*<sup>2</sup> and *Diamond v Chakrabarty*<sup>3</sup>. In *Funk*, the patentee discovered that certain strains of nitrogen-fixing bacteria associated with certain plants did not mutually inhibit each other, so it patented mixed cultures of nitrogen-fixing species capable of inoculating a broader range of plants than single-species cultures. The Supreme Court held that the bacteria’s cooperative qualities were a “work of nature” and the bacterial mixture was not patentable. The court reasoned that no species had acquired a different property or use in the mixture<sup>4</sup>.

In *Chakrabarty*, the Supreme Court held that claims to certain bacteria were patent eligible. In particular, these were man-made bacteria genetically engineered with four naturally occurring DNA plasmids each of which enabled the breakdown of a different component of crude oil. The patentee had created a bacterium unlike any in nature either in structure or function – namely, the ability to break down multiple components of crude oil, a significant benefit for more efficiently treating oil spills. The bacteria, according to the court, were a patent-eligible “non-naturally occurring manufacture or composition of matter – a product of human ingenuity ‘having a distinctive name, character [and] use’”. The court distinguished *Funk* on the ground that Chakrabarty’s bacteria had “markedly different characteristics from any [bacterium] found in nature<sup>5</sup>”.

On this neatly arranged legal landscape, each of the three *Myriad* judges followed different paths. For Judge Lourie, who earned an advanced degree in chemistry and has industry research experience, isolated DNA

was “markedly different” from anything in nature because it was in fact a different molecule than human DNA; covalent bonds were broken in isolating it. Judge Lourie did not see this as just unpatentable “purifying”. He found it irrelevant that the information content of isolated DNA was the same as the respective section of human DNA from which it came and that there may be no difference in “physiological use or utility”.

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Judge Bryson came to the opposite conclusion. In his view, there was no “magic” to breaking a covalent bond and the structural changes attendant to an isolation process did not make the isolated product itself patentable. He noted that the patent claimed any isolated DNA according to its particular coding sequence and the coding sequence was identical to that of the gene in nature. In his view, the claimed isolated gene did not differ in function because of the isolation process or the structural differences from nature. He argued that, per *Prometheus*, a patent for a product of nature must include an inventive concept significantly more than changes incidental to the naturally occurring product.

Judge Moore parsed the isolated DNA claims further. She found that “short” isolated DNA sequences were patent eligible because their utilities were markedly different from human DNA, including having uses as probes and primers. However, Judge Moore believed that longer strands of DNA that included most or all of the human gene presented “a more difficult case”. She agreed with Judge Lourie that the structure was in fact

technically different from a human DNA molecule, but she also agreed with Judge Bryson that the structural difference gave rise to no enlargement of utility. If the court were “deciding the case on a blank canvas”, she might have found the claims unpatentable. But, given a long history of the US Patent and Trademark Office (USPTO) allowing these patents, and the thousands of issued patents depending on these kinds of claims, she concluded that the *status quo* should be maintained – the subject matter should remain patent eligible and any change should come from Congress, the legislature.

So what is a practitioner to make of this? First, the basic legal rules espoused by each of the judges in *Myriad* were generally consistent with one another and Supreme Court precedent regarding patent-eligibility, including *Prometheus*. The *Myriad* ruling itself thus does not fundamentally change the patent eligibility analysis.

At the end of the day, the decision appears to come down to individual judges diverging in their personal views of whether certain differences between a patented product and a product of nature are sufficient to result in an invention of something beyond that law of nature/product of nature – with the majority outcome of eligibility influenced by a long history of the USPTO allowing these kinds of patents. Judge Moore’s middle ground reasoning therefore is eminently sensible.

Practitioners should carefully watch the *Myriad* decision and other decisions in this area. Given the controversy, further Supreme Court review may be very welcome. For the time being, isolated DNA sequences are still potentially patentable.

#### Footnotes

1. Appeal No 2010-1406, 2012 WL 3518509 (Fed Cir 16 August 2012).
2. 333 US 127 (1948).
3. 447 US 303 (1980).
4. 333 US at 129-32.
5. 447 US at 309-10.

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